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Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201
Attn: OCCIO-9993-IFC

RE: Interim Final Rules for Group Health Plans and Health Insurance Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act

To Whom It May Concern:

The U.S. Chamber of Commerce (the “Chamber”) submits these comments in response to the Interim Final Rules for Group Health Plans and Health Insurance Relating to Internal Claims and Appeals and External Review Processes under the Patient Protection and Affordable Care Act (“IFRs” or “regulations”), which were published in the Federal Register on July 23, 2010.¹ The IFRs provide guidance pursuant to the statutory language of the Patient Protection and Affordable Care Act (the “Affordable Care Act” or “PPACA”). As with other guidance under this Act, the IFRs were published jointly by the Department of the Treasury, the Department of Labor and the Department of Health and Human Services (the “Departments”).² In addition, on August 23, 2010, the Department of Labor issued Technical Release 2010-01 relating to these claims and appeals processes. The Department also issued Technical Release 2010-02 on September 20, 2010.

The Chamber is the world’s largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. These comments have been developed with the input of member companies with an interest in improving the health care system.

¹ Group Health Plans and Health Insurance Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330-64 (July 23, 2010) (to be codified at 26 C.F.R. pts. 54 and 602; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147) [hereinafter Internal Claims and Appeals and External Review Processes].

² Pursuant to the request in the IFRs, the Chamber is submitting these comments to one of the Departments - The Department of Labor, with the understanding that these comments will be shared with the Department of Health and Human Services and the Department of Treasury as well.

OVERVIEW

The U.S. Chamber of Commerce and our member companies want a health care system in which quality health care is readily available at an affordable price, a goal central to the Affordable Care Act. In such a system, reasonable claims procedures are essential for resolving benefit disputes. However, claims procedures requirements should not undermine the goal of affordable care by imposing complex and costly procedures.

Currently, ERISA group health plans (both insured and self-insured) must comply with internal claims and appeals requirements adopted by the Department of Labor during the Clinton administration.³ Additionally, a majority of states have created external review requirements with which insured plans must comply.⁴ The ERISA claims procedures have worked well when considering how infrequently health benefit claims are litigated. This has helped control what might otherwise have been a significant administrative cost. Although plaintiffs' lawyers might prefer a more litigation-friendly environment, the present rules strike a reasonable balance between protecting participant rights and minimizing dispute resolution expenses.

We believe it is reasonable to extend the ERISA claims procedures to the individual insurance market, to consider revisions to the ERISA claims procedures in light of existing experience, and to assess how external review procedures can constructively be included in the ERISA claims procedures. Unfortunately, many of the changes made by the Interim Final Regulations will undermine the goal of affordable care by increasing administrative expenses and by incenting plans to provide claimed benefits that are not due under the plan in order to avoid the expense of dispute resolution. This added expense, and the greater frequency of disputes, will discourage employers from extending health care benefits and will raise premiums for participants. Further, many plans and issuers will find it impossible to comply with the proposed requirements contained in the IFRs for plan years beginning on or after September 23, 2010.⁵

To advance the paramount goal of providing affordable health care, we respectfully request that the Departments withdraw the interim final rules and issue a proposed rule, relying, in the interim, on the deeming authority granted to the Departments by statute.⁶ For plans that do not already conduct external reviews, the Secretary should (as stated in the statute) set out an interim minimum standard that requires plans to make some meaningful progress toward establishing external review by no later than the 2012 plan year.⁷ In following this approach, the Departments will meet the statutory obligations (plans will be implementing an external review

³ Final Rule on Claims Procedure, 65 Fed. Reg. 70, 246 -70271 (November 21, 2000) (codified at 29 C.F.R. pt. 2560).

⁴ According to The Henry J. Kaiser Family Foundation, 44 states including the District of Columbia in 2008 had external review processes in place that plans were required to follow. (Available at: <http://www.statehealthfacts.org/comparabletable.jsp?cat=7&ind=361>).

⁵ The claims, appeals and external review rules only apply to "non-grandfathered" plans so this point only applies to plans that do not have grandfathered status.

⁶ Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1001(5), 124 Stat 119 (2010), as amended by §10101 (g), amending Public Health Service Act by creating §2719 (c).

⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1001(5), 124 Stat 119 (2010), as amended by §10101 (g), amending Public Health Service Act by creating §2719 (b)(2)((A) and (B) (emphasis added): "A group health plan and health insurance issuer offering group or individual health insurance coverage *shall implement an effective external review process that meets minimum standards established by the Secretary through guidance*... if the applicable state has not established an external review process that meets the minimum requirements ...or if the plan is a self-insured plan that is not subject to State insurance regulation (including a State law that establishes an external review process...)."

process beginning on or after September 23, 2010) and the Departments will have an opportunity to fully vet any changes to the current internal and external review procedures. Following a comment period sufficient to allow for stakeholders to provide important and critical feedback and for the Departments to thoroughly review comments and contemplate alternatives that address issues raised in the comments, a final rule should be issued.

A. The IFR time frame is inappropriate and impossible.

The IFRs add several significant and complex requirements that plans and issuers cannot implement for plan years beginning on or after September 23, 2010. While the Chamber appreciates the efforts of the Departments to provide a grace period for some of these changes pursuant to Technical Release 2010-02, plan sponsors and issuers will require at least 12 months to make the system-wide changes necessary to implement compliant information systems, workforce training and staffing, and market research. These burdensome and costly changes would do nothing to make healthcare more affordable. Rather, the IFRs would increase the cost and complexity of providing health care and discourage employers from offering health plan coverage. In the points we discuss below, we hope to highlight for the Departments the extensive burden that these requirements place on plans and issuers.

B. Improper regulatory process: traditional informal rulemaking should be used

These IFRs contemplate tremendous changes and will implement exceedingly complex processes before comments from stakeholders can be carefully evaluated. Given the dramatic impact of these regulations, we respectfully contend that it is improper for the Department to adopt a process that negates the opportunity to consider comments before the changes become effective. Instead, we request that the Departments alter their course and follow a regulatory process which will be far more likely to lead to the thoughtful creation of appropriate claims and appeals procedures.

In addition to the policy reasons that support an altered course, we believe that the Departments were improper in evading the traditional regulatory process. In the preamble, the Departments base the decision and authority to issue the regulations as Interim Final Rules on two grounds. First, the Departments assert that the Administrative Procedure Act (APA) is not applicable because of specific statutory authority.⁸ Second, the Departments assert that even if the APA were applicable, there is “good cause” for issuing interim final rules. Specifically, the preamble suggests that it would be “impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed.”⁹ With a recent court decision finding that Departments cannot rely on statutory authority alone, we question the underlying good cause argument.

⁸ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,337. “The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.”

⁹ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,337: “In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, the internal claims and appeals and external review provisions of the

1. IFRs evade the protections afforded under the APA

The APA requires that federal agencies, prior to the promulgation of any regulation, publish in the Federal Register a general notice of proposed rulemaking. After such notice is published, “the agencies shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for writing presentation.” Although the notice and comment period occur when IFRs are issued, the fundamental protections afforded under the APA are not extended. Unlike traditional informal rulemaking which requires agencies to consider the comments presented and provide a “concise general statement” of the basis and purpose of the final rules, this IFR process will apply the full force of many provisions of the interim final regulations just two days after comments are filed.

The traditional informal rulemaking requirements are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.¹⁰ In bypassing the informal notice and comment period required by the APA, the Departments have dispensed with the opportunity to receive and consider feedback before the regulations take effect. Instead, we urge the Departments to listen to these concerns and structure regulations that encourage affordable care: if these interim final rules take effect, these actions of the Departments will be tremendously damaging.

2. Statutory authority to promulgate IFRs is not absolute

In the preamble of the IFRs, the Departments cite the statutory authority¹¹ to promulgate interim final rules. The statutory authority cited by the IFRs refers to changes that the Health Insurance Portability and Accountability Act¹² (HIPAA) made by adding the below language to the referenced provisions of Employee Retirement Income Security Act (ERISA), the Internal Revenue Code (IRC) and the Public Health Service Act (PHSA).

The Secretary, consistent with section 104 of the Health Care and Portability and Accountability Act of 1996, *may* promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part. The

Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final regulations require significant lead time in order to implement.”

¹⁰ *Coalition for Parity v. Sebelius*, 2010 U.S. Dist. LEXIS 60941, 18 (D.D.C. June 21, 2010).

¹¹ Under section 9833 of the Code, section 734 of ERISA and sections 2792 of the Public Health Service Act, which authorizes the Secretaries of the Treasury, Labor, and HHS to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of Subtitle B of Title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA sections 715 and Code section 9815.

¹² Pub. L. No.104-191, §§ 101, 102, 401, 110 Stat. 1936, 1951, 1976, 2092 (1996).

Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this part.¹³

The provisions in the PPACA that these IFRs implement¹⁴ amend the same sections of ERISA, the Internal Revenue Code and the Public Health Service Act that HIPAA amended with the above language. However, although this text clearly gives the Secretaries authority to promulgate interim final rules to carry out these sections, the District of Columbia's District Court recently stated that this authorization is not solely sufficient to authorize the promulgation of interim final rules.¹⁵ The court has recently ruled that, "finding that Congress authorized the promulgation of interim final rules [on a permissive basis] does not end the inquiry."¹⁶ The statute may be read to require that interim final rules be promulgated either with notice and comment or with "good cause" to forego notice and comment. By explicitly stating in the IFRs that the Departments were promulgating the IFRs without notice and comment pursuant to the good cause exception in §553, analysis of the [Departments'] action, according to the court in *Coalition for Parity v. Sebelius*, "should be analyzed in that context rather than relying solely on the authorization for interim final rulemaking provided by HIPAA."¹⁷

3. "Good cause" argument flawed

Just as in the IFRs issued to implement the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008,¹⁸ the Departments make a "good cause" assertion in these IFRs. However, given the substance of the regulations and the significant changes that the IFRs mandate, the Department's argument that traditional formal rulemaking would be "impracticable and contrary to public interest" is faulty.¹⁹ Plans and issuers cannot implement the requirements stipulated nor comply with the processes in the interim final rules within the sometimes extended timeframe mandated, even with the issuance of interim final regulations. We recommend that the agencies withdraw the interim final regulations since the regulations go beyond the requirements of the statute and provide a system that is overly complex and unnecessary. Even with a grace period, various issues need to be examined and fully vetted to

¹³ 29 U.S.C. § 1191c, 26 U.S.C. § 9833 (replacing "part" with "chapter,") and 42 U.S.C. §300gg-92 (replacing "part" with "subchapter"). This regulatory authority covers part 7 of Subtitle B of Title I of ERISA (29 U.S.C. §§ 1181-91c), Chapter 100 of the Internal Revenue Code (26 U.S.C. §§ 9801-33), and Part A of Title XXVII of the Public Health Service Act (42 U.S.C. §§ 300gg to 300gg-92) (emphasis added).

¹⁴ §1001 of the Patient Protection and Affordable Care Act amends the Public Health Service Act by adding §2719 Internal Claims and Appeals and External Review Processes.

¹⁵ *Coalition for Parity v. Sebelius*, 2010 U.S. Dist. LEXIS 60941, 18 (D.D.C. June 21, 2010).

¹⁶ *Coalition for Parity v. Sebelius*, 2010 U.S. Dist. LEXIS 60941, 26(D.D.C. June 21, 2010).

¹⁷ *Id.*

¹⁸ Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 75 Fed. Reg. 5410-5451 (February 2, 2010) (codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 146).

¹⁹ "Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final regulations require significant lead time in order to implement. These interim final regulations require plans and issuers to provide internal claims and appeals and external review processes and to notify participants, beneficiaries, and enrollees of their rights to such processes. Plans and issuers will presumably need to amend current internal claims and appeals procedures, adopt new external review processes, and notify participants, beneficiaries, and enrollees of these changes before they go into effect. Moreover, group health plans and health insurance issuers subject to these provisions will have to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits. In some cases, issuers will need time to secure approval for these changes in advance of the plan or policy year in question."

determine their efficacy and potential legality. Consider the additional complications and problems that will arise if, in good faith, plans start to implement the changes required by the IFRs only to have the agencies change the processes.

Furthermore, the underlying statutory language in the PPACA does not reflect Congress's clear intent that the APA notice and comment procedures not be followed. Instead, the language in the law does just the opposite; the statute includes deeming language²⁰ that would facilitate compliance with the deadline while traditional informal rulemaking occurs. Therefore, the Departments acted improperly in issuing these regulations as Interim Final Rules.

4. Practical consideration

Compliance with the new rules will be directly proportionate to the number of locations in which guidance is presented by the Departments. Already, the Departments have issued guidance regarding claims and procedures in the IFRs and two Technical Releases. This invariably leads to confusion and additional failures to comply. It also is a case in point for the Chamber's position regarding the need to use the normal APA process for issuing guidance in this important area. The Departments issued IFRs and Technical Release 2010-01. Then, based on public comments, they issued a partial grace period. The Chamber expects the Departments to make additional changes as more public comment is considered. The importance and complexity of these provisions of PPACA cry out for the use of the normal APA regulatory process.

SUBSTANTIVE CONCERNS:

In addition to the significant procedural concerns discussed above, the Chamber has a number of critical substantive concerns with the two different processes that the IFRs contemplate implementing: (A) the Internal Claims and Appeals Process; and (B) the External Review Process.

A. Internal claims and appeals process

The Internal Claims and Appeals Process regulations require plans to comply with the requirements under the DOL claims procedure regulation (ERISA) and six new requirements in the areas of adverse benefit determination, 24-hour notice for Urgent Care Claims, Fair and Full Review, Conflicts of Interest, Additional Disclosure and Content of Notice, and Failure to Comply.²¹ With regard to the Internal Claims and Appeals Processes as it relates to group coverage, the Chamber has significant, substantive concerns with five of the six new requirements.

²⁰ Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1001(5), 124 Stat 119 (2010), as amended by §10101 (g), amending Public Health Service Act by creating §2719 (c).

²¹ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,332 and 42,358-61 (to be codified at §147.136(b)).

1. Improper expansion of the definition of adverse benefit determination

Not all rescissions should be considered an appealable adverse benefit determination.²² As the Chamber previously discussed in comments filed in response to the “rescission” IFRs,²³ the IFRs improperly create an entitlement to mistaken coverage or benefits. When the enrollee had neither a reasonable expectation of coverage, nor a right to coverage, under plan or contract terms or otherwise applicable law, it is wrong to treat the correction of that error as a “rescission.” Hopefully, the agencies will correct the rescission IFR to make it clear that correcting such a coverage error is not a rescission. As such, a correction of this type should not be treated as an adverse benefit determination.

2. Unreasonable changes to ERISA time frames for decisions regarding urgent care claims

The regulations impose a new outside limit on the time frame within which a plan must notify a claimant of a benefit determination for an urgent care claim. Following the end of the grace period described in Technical Release 2010-02, the IFRs require that notification occur “as soon as possible” but “not later than 24 hours after the receipt of the [urgent care] claim by the plan or issuer.” Prior requirements mandated that notification, in the case of urgent care claims, occur as soon as possible but not later than 72 hours after the receipt of the claim.²⁴

In order for plans to comply with this new and arduous deadline, workforce and staffing changes would have to be made for plans to conduct claim review on a **24 hour a day, 7 days a week basis**. Not only are plans and issuers unable to develop the capacity to review claims on a continuous basis in time to comply with the regulatory deadline, we believe that this requirement is unreasonable. Responding quickly to enrollees in these circumstances is extremely important; however, these benefit determinations are made based on the information supplied by health care providers, the majority of which are not staffed to exchange clinical information and medical records with plans and issuers on a 24-hour basis. The additional expense for providers and plans to comply with this requirement seems to significantly outweigh whatever small benefit this change may create.²⁵

²² Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,358 (to be codified at §147.136(a)(2)(i): “An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in §147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time.)”. Id, 75 Fed. Reg. at 43,359 (to be codified at §147.136(b)(2)(ii)(A): “an ‘adverse benefit determination’ includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503-1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128 of this part.)”

²³ U.S. Chamber of Commerce Comments to Interim Final Rules for Group Health Plans and Health Insurance Coverage Regarding Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions and Patient Protections under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 37,188–37,241 (June 28, 2010) (to be codified at 26 C.F.R. pts. 54 & 602; 29 C.F.R. pt. 2590; 45 C.F.R. pts. 144, 146 and 147) [hereinafter Preexisting Condition Exclusion, et al].

²⁴ 29 C.F.R. 2560.503-1(f)(2)(i).

²⁵ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,333. The preamble to the IFR tries to justify the shortening of the response period by two-thirds because “electronic communication will enable faster decision-making today than in the year 2000 when the final DOL claims procedure regulation was issued.” Electronic communication, including internet and email, were uniformly and extensively used by health plans, insurers, and TPAs in 2000 and we respectfully submit that there is no factual basis for this assertion. The human factor is the critical component to proper claims determination, and the Departments should give plans the opportunity to explain why the Departments’ assumptions are unfounded. Rushed decision making will not lead to affordable quality care, but only poorer claims decisions and more expense. Significantly, the IFRs do

This new overly arduous deadline is also not required by statute; there is no specific mention in the new PHSA §2719 created by PPACA of urgent care claims or time frames for review. Further, there has been no indication that the current time frame requirements under ERISA are insufficient. Therefore, we recommend that the Departments retain the current urgent care notice timeframe created by ERISA and extend this deadline to the urgent care notice requirements for internal claims and appeals processes.

3. Conflicts of interest

The regulations require that the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in the making the decision.²⁶ We request clarification with regard to this requirement as it relates to self-insured plans. Self-insured plans have individuals on review panels and we expect that this will continue to be permitted. We respectfully suggest that the Departments clarify that litigation should not be permitted to occur simply based on an allegation that the plan's or its sponsor's employees participate in the internal review of claims decisions. Employers who provide health care want employees to receive the health benefits that have been promised and want to avoid wasteful administrative procedures. ERISA procedures already provide means for identifying and correcting bias or conflicts of interest in the claims procedure.²⁷

4. Inappropriate notice content requirements

The Chamber has several concerns with this requirement.

Overly burdensome requirement to provide notice in a culturally and linguistically appropriate manner

The regulations impose extensive procedures on plans and issuers to provide relevant notices in a culturally and linguistically appropriate manner.²⁸ This portion of the regulation imposes two costly and complex elements:

1. The plan administrator or issuer must determine whether assistance is necessary by assessing the number of plan participants that are literate only in the same non-English language.
2. If assistance is necessary according to thresholds imposed by the regulations, the plan must:
 - Include a statement in the English version of all notices offering the provision of such notices in the non-English language;
 - Provide all subsequent notices in the same non-English language, if a claimant requests, and

not shorten any time periods applicable to persons appealing claims denials or seeking external review, even in alleged urgent care situations.

²⁶ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,359 (to be codified at §147.136(b)(2)(ii)(D).

²⁷ See *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105 (2008); *Denmark v. Liberty Life Assur. Co.*, 566 F.3d 1 (1st Cir. 2009), *Hobson v. Metropolitan Life Ins. Co.*, 574 F.3d 75 (2d Cir. 2009); *Doroshov v. Hartford Life & Acc. Ins. Co.*, 574 F.3d 230 (3d Cir. 2009); *Stone v. Unocal Termination Allowance Plan*, 570 F.3d 252 (5th Cir. 2009); *Love v. Nat'l City Corp. Welfare Benefits Plan*, 574 F.3d 392 (7th Cir. 2009); *Abati v. Alta Health & Life Ins. Co.*, 421 F.3d 955 (9th Cir. 2006)

²⁸ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,363 (to be codified at §147.136(e)(1).

- Ensure that customer assistance processes provide assistance in the appropriate non-English language.

While we support the goal of ensuring that claimants understand notices and are therefore able to exercise their right to appeal an adverse benefit determination, the requirements delineated in the regulations are exceedingly burdensome in a number of ways. It will be difficult for plans and issuers to comply with these requirements by the end of the grace period provided in Technical Release 2010-02, and it will be expensive and administratively burdensome for plans to follow. The focus of reform should be on curbing the rising cost of health care. This unnecessary and burdensome requirement will only undercut this goal. Additionally, the linguistically appropriate requirements of this IFR will make complying with MLR requirements even more difficult.

Improper definition of “information sufficient to identify the claims involved”

The preamble and the regulations state that plans “must ensure that any notice of adverse benefit determination includes information sufficient to identify the claim involved.”²⁹ We agree that this is an appropriate goal and agree with the first few content requirements listed: “the date of service, the health care provider, and the claim amount (if applicable).”³⁰ It is also important that notices include denial codes and explanations and information on how to file an appeal.³¹ However, the regulations go on to dictate that plans include “the diagnostic code (such as an ICD-9 code, ICD-10 code or DSM IV code), the treatment code (such as a CPT code), and the corresponding meanings of these codes.”³² These requirements are *not* appropriate for a number of reasons including relevancy, impossible compliance, cost and administrative burden on the plan/issuer, privacy and statutory authority. The goal of ensuring that an enrollee is able to identify a claim can be achieved with far less onerous requirements.

Typically, an explanation of benefits (EOB) informs an enrollee/participant of the extent to which his or her medical services have been paid. EOBs currently include the date of service, the provider’s name, the patient’s name, the amount charged by the provider and the amount paid by the plan. This information is sufficient to identify the medical services to which the EOB refers. In the vast majority of cases, EOBs are not appealed. In the event a question or dispute arises, other specific information is readily available.

Including the highly sensitive medical information contemplated by the IFR is unnecessary and would only complicate the EOBs, while also creating significant privacy concerns. Forcing plans to mail this private, sensitive clinical information to participants increases the risk of inadvertent disclosure of protected health information. Patients may not want details of their medical treatment fully disclosed in an EOB.

²⁹ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,333. Id., 75 Fed. Reg. at 43,360 (to be codified at §147.136(b)(2)(ii)(E)(1)).

³⁰ Id.

³¹ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,360 (to be codified at §147.136(b)(2)(ii)(E)(2), (3) & (4)).

³² Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,360 (to be codified at §147.136(b)(2)(ii)(E)(1)).

Imagine reading the following on an EOB for your spouse: *ICD-9 code: 079.53 and Description: Human Immunodeficiency Virus, Type 2 {HIV2}*. This detail is available if a question or appeal arises; it serves no purpose on the vast majority of EOBs.

In addition to threatening Americans' privacy and unnecessarily printing confidential medical information, the changes would require extensive internal reprogramming and processing for providers, insurers, third party administrators, and plans. The implementation process for including this clinical information would require 12 to 18 months. Once again, this raises health care costs with no real benefit. This unnecessary and burdensome requirement will only undercut this goal and lead to greater administrative costs, making health care more expensive. Additionally, as plans and issuers struggle to comply with new medical loss ratios (MLR) requirements, these changes will mandate additional administrative costs and make complying with MLR requirements even more difficult. There is no way for plans to comply with these requirements even by the deadline imposed, and there is no purpose advanced by requiring plans to go through the expensive and burdensome process.

For the critical reasons discussed, we respectfully request that the Departments revise the requirements listed in §147.136(b)(2)(ii)(E)(1) to include only the information an enrollee would need to identify the claim: the date of service, the provider's name, the patient's name, the amount charged by the provider and the amount paid by the plan.

5. Harmless error must not permit enrollees to sidestep the internal process

Both procedurally and ideologically, permitting a *de minimis* or harmless error to entitle an enrollee to immediately initiate external review and file a lawsuit is bad policy. The regulations state that "in the case of a plan or issuer that fails to strictly adhere to all the internal claims and appeals requirements with respect to a claim," an individual "is deemed to have exhausted the internal claims and appeals process...regardless of whether the plan asserts that it substantially complied."³³

Claim procedures requirements are already so complex (and under the IFR would become even more complex) that requiring strict compliance will severely erode the entire claims process, essentially making it optional for any nitpicking claimant or representative. This would permit individuals to circumvent the internal claims and appeals process and initiate an external review and pursue any available remedies under applicable law, such as filing a lawsuit. While plans will never be able to achieve perfect compliance, they will need to incur extra expense to limit good faith mistakes. Further, even when plans do achieve perfect compliance, they will have to defend claims that they failed to comply perfectly.

This "perfection standard" is particularly troublesome and problematic given that these IFRs require plans and issuers to comply with numerous new complex, rigorous, and extensive requirements under an impossible timeframe, even under the grace period described in Technical Release 2010-02. Plans will be making significant changes to adopt the new measures and procedures required by the regulations and will be under tremendous pressure to do so quickly.

³³ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,360 (to be codified at §147.136(b)(2)(ii)(F)).

It is virtually impossible to imagine that any plan will be able to “strictly adhere to all the new requirements.”

Ideologically, by imposing this unforgiving new standard, the regulations negate the important internal claims and appeals process that they bolster. This will result in an onslaught of more costly and difficult filings through the external review process. It seems contrary to reason to permit individuals to immediately sidestep the internal process in order to pursue a more arduous and costly process.

In addition, this standard threatens to impose unreasonable excise taxes on employers. The Notice of Interim Guidance issued on External Review, Internal Claims and Appeals under PPACA issued August 26, 2010 by the Departments, and the DOL Technical Release 2010-01 make the parenthetical statement that “if a plan complies with one of the interim [external review] compliance methods of this technical release, no excise tax liability should be reported on IRS Form 8928 with respect to PHS Act section 2719(b).” This appears to be an unofficial and barely visible warning that the IRS expects employers to report PPACA errors on IRS Form 8928, with attendant excise tax liability of \$100 per day per individual impacted. Small employers offering health benefits to 100 employees could face penalties of more than \$10,000 per day for PPACA errors.

It is unreasonable to impose such taxes for EOB noncompliance or other procedural errors that hurt no one and that arise from the difficulty employers will have in complying on short notice with new, complex and confusing PPACA group health plan requirements. Despite the recently released sub-regulatory guidance setting forth “an enforcement grace period for compliance with certain provisions with respect to the internal claims and appeals,” there are no protections for plans and issuers from claimants trying to enforce the strict compliance standard.³⁴ Employers and insurers need time to develop procedures that are reasonably designed to ensure compliance, as well as time to promptly take action to correct incidents of noncompliance. The IRS should postpone for at least one year any Form 8928 reporting requirements or excise tax liability for PPACA noncompliance. At a minimum, the ‘strict compliance’ requirement of the IFR should be abandoned as unreasonable, punitive, and inimical to the goal of affordable care.³⁵

However, if the strict compliance rule is to be retained, then the Agencies should add a proviso to prevent overly litigious claimants. It already is common for ERISA claimants to make excessive discovery and other demands during the course of claims determinations. The new strict compliance rule would make it more dangerous than ever for a plan or issuer to reject unreasonable demands. Therefore, if the strict compliance standard must be retained, it should be softened by the addition of a proviso to the effect that: “It is the Agencies' intent that claims,

³⁴ Technical Guidance 2010-02, Internal Claims and Appeals under the Patient Protection and Affordable Care Act, U.S. Department of Labor, September 20, 2010.

³⁵ Id. We appreciate the efforts of the sub-regulatory guidance issued on September 20, 2010 to address this issue with respect to several standards in the IFR. “Specifically, with respect to standards regarding the timeframe for making urgent claims decisions, providing culturally and linguistically appropriate manner, broader content and specificity in notices and substantial compliance, If the Department of Labor and the Internal Revenue Service (IRS) will not take any enforcement action against a group health plan, and HHS will not take any enforcement action, during the grace period, against a self-funded nonfederal governmental health plan, that is working in good faith to implement such additional standards but does not yet have them in place.⁵ [Footnote 5]: Moreover, if a plan takes such steps towards compliance, no excise tax liability should be reported on IRS Form 8928 with respect to PHS Act section 2719(b) with respect to a failure to meet any of these particular standards.”

appeals, and reviews be handled efficiently and expeditiously, and not turned into quasi-litigation; hence, a plan will not violate the strict compliance standard by refusing to accommodate unreasonable claimant demands, such as demands for documents or information that are unlikely to provide material support for the claim."

6. *Encourage reasonable dispute resolution without wasteful administrative expense*

The internal claims process should permit an informal exchange of information between the insurer/TPA and the participant to resolve the claims dispute. Too often the IFR imposes rigid time periods or procedures that appear to encourage litigation instead of communication.

For example, the IFRs provide that a plan must provide the claimant with any new evidence considered, relied upon, or generated sufficiently in advance of the appeal decision to enable the claimant to respond before the decision. This reverses the holdings of several courts of appeal that ERISA does not require the plan administrator to allow claimants to respond to new evidence assembled by the plan in response to the claimant's appeal.³⁶ If the Departments believe that claimants should be permitted to respond to such new information in the claims procedure, then the time periods of the appeal process should be extended to reasonably accommodate these information exchanges. Such exchanges can promote resolution of claims without litigation and further the goal of affordable health care.

B. External review process

The regulations require plans to comply with a State external review process, if it applies to and is binding on an issuer and includes the minimum consumer protections in the National Association of Insurance Commissioners (NAIC) Model Act. If no state external review process applies or is binding on the plan or issuer, then the plan or issuer must comply with the Federal external review process.³⁷ With regard to the External Review Process as it relates to group coverage, the Chamber has four critical substantive concerns.

1. *Inconsistent and overly broad scope of federal external review process*

The regulations are inconsistent with the statutory language of the PPACA. There are significant discrepancies between the scope of the external review processes as contemplated by the statutory language of the PPACA and that delineated in the regulations.

The statute requires that applicable state external review processes must include at a minimum the consumer protections set forth in the Uniform External Review Model Act (the "NAIC Model Act") as promulgated by the National Association of Insurance Commissioners (NAIC).³⁸ And when a state has either not established an external review process that meets these [NAIC

³⁶ See, e.g., *Metzger v. Unum Life Ins. Co.*, 476 F.3d 1161 (10th Cir. 2007); *Rittenhouse v. United Health Group Long Term Disability Ins. Plan*, 476 F.3d 626 (8th Cir. 2007). But see *Abram v. Cargill, Inc.*, 395 F.3d 882 (8th Cir. 2005) (discussing regulations in effect in 2000); *Harris v. Aetna Life Ins. Co.* 379 F .Supp. 2d. 1366 (N.D. Ga. 2005).

³⁷ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,361 (to be codified at §147.136(c)(1)).

³⁸ Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1001(5), 124 Stat 119 (2010), as amended by §10101 (g), amending Public Health Service Act by creating §2719 (b)(1).

Model Act] requirements³⁹ or if a plan is not subject to state insurance regulation,⁴⁰ the statute states that the plan or issuer shall implement an effective external review process that meets the minimum requirements established by the Secretary that is similar to the NAIC's Model Act. However, the scope of the Federal external review process is substantially greater than the scope outlined by the NAIC for the states.⁴¹

Since only adverse benefit determinations are subject to external review, the NAIC Model Act, in defining an adverse benefit determination, stipulates that only the following determinations are within the scope of external review:

A determination (by a health carrier or its designee utilization review organization) that an admission, availability of care, continued stay or other health care service that is a covered benefit does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness, and the requested service or payment for the service is therefore denied, reduced or terminated.⁴²

The regulations take a similar approach with regard to the scope of state external review processes by stipulating that a state's process "must provide for the external review of adverse benefit determinations (including final adverse internal benefit determinations) by issuers that are based on the issuer's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness of a covered benefit."⁴³

The regulations' "deemed exhaustion rule" substantially expands the scope of the Federal external review process beyond the statutory requirements and current review processes. Under this rule, an issuer's failure to strictly adhere to all the requirements with respect to a claim will permit an enrollee to initiate an external review process regardless of the issue in question.

As discussed earlier on page 9 of these comments, the regulations deem an exhaustion of the internal claims and appeals process when a plan fails to strictly comply with the notice requirements. This is improper from both a procedural and policy standpoint. This regulation will result in increased expenses as plans are forced to permit non-prejudicial and easily remedied errors to be reviewed and possibly litigated externally. It creates a venue for individuals to pursue external appeal on anything and everything.

Under current law, internal review is encouraged and required, unless there is reason that such a review would be futile or if the participant is not informed of the review process. Similar standards should apply here. If there is substantial compliance with the internal review process and the administrator acted in good faith, then deemed exhaustion should not apply. We urge the

³⁹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1001(5), 124 Stat 119 (2010), as amended by §10101 (g), amending Public Health Service Act by creating §2719 (b)(2)(A).

⁴⁰ Patient Protection and Affordable Care Act, Pub. L. No. 111-148 §1001(5), 124 Stat 119 (2010), as amended by §10101 (g), amending Public Health Service Act by creating §2719 (b)(2)(B).

⁴¹ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,363 (to be codified at §147.136(d)(1)).

⁴² Uniform Health Carrier External Review Model Act, National Association of Insurance Commissioners, April 2010, 76-33, Section 3, (A).

⁴³ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,361 (to be codified at §147.136(c)(2)).

Departments to revise this regulatory language (for which there is no basis in statute) to preserve the internal claims and appeals process and permit plans to properly handle and correct de minimis errors internally.

2. *Nominal fee and no minimum threshold will lead to an avalanche of claims under the State external review process*

We appreciate the importance of preserving the ability for individuals to file appeals for significant and prejudicial determinations. However by so severely limiting the filing fee⁴⁴ and failing to impose a minimum threshold⁴⁵, the Regulations create perverse incentives for individuals to abuse the external appeals process. As a result, there will likely be an avalanche of costly and time-consuming external review claims filed with respect to minor and unmeritorious claims by individuals isolated from the cost of these reviews with no reason not to appeal any and all adverse benefit determinations.

3. *De novo review affords no deference to internal claims and appeal process findings and rewrites ERISA*

While we understand the importance of external review, the Chamber and its member companies also believe that significant and valuable information can be ascertained during the internal review process. Both the NAIC Model Act and the Technical Guidance from the Department of Health and Human Service's Office of Consumer Information and Insurance Oversight sets forth procedures for external review for self-insured group health plans that redefine the level and standards for the external review.

According to the NAIC Model Act, "in reaching a decision, the assigned independent review organization is not bound by any decisions or conclusions reached during the health carrier's utilization review or the health carrier's internal grievance process."⁴⁶

Similarly the technical guidance that sets forth interim procedures for the federal external review processes states that "[i]n reaching a decision, the examiner will review the claim de novo and not be bound by any decisions or conclusions reached during the health insurance issuer's internal claims and appeals process."⁴⁷

⁴⁴ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,361-2 (to be codified at §147.136(c)(2)(iv)): "the issuer against which a request for external review is filed must pay the cost of conducting the external review... may require a nominal filing fee from the claimant requesting external review ... which to be considered nominal ... must not exceed \$25... and the annual limit on filing fees for any claimant within a single plan year must not exceed \$75."

⁴⁵ Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,362 (to be codified at §147.136(c)(2)(v)): "The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review."

⁴⁶ Uniform Health Carrier External Review Model Act, National Association of Insurance Commissioners, April 2010 76-44 Section 8.D. (2)

⁴⁷ Technical Guidance for Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review for Health Insurance Issuers in the Group and Individual Markets under the Patient Protection and Affordable Care Act, Department of Health and Human Services, Office of Consumer Information and Insurance Oversight, Section II. A 5 a., page 8-9.

This is a significant and fundamental change for plans and issuers that requires external reviewers to start over and conduct a de novo review of the adverse benefit determination. Previously, under ERISA, reviewers were required to defer to findings and determinations made by plans and issuers during the internal review process. Currently, if the administrator is given discretion to determine eligibility, interpret the plan provisions, and make benefit determinations, then the administrator's decision should be upheld unless unreasonable or arbitrary and capricious. If an IRO conducts a de novo review and its decision is binding on all parties, what standards will be used by the IRO? Will the policy be interpreted against the drafter? Will an administrator's interpretation of ambiguous language be upheld if it is a reasonable interpretation? Since the IRO will make ultimate determination, will IRO be fiduciary? Although federal common law has developed in the courts regarding review of administrators' decisions, they obviously would not apply. The question remains: what standards will apply?

This dramatic change was not contemplated by the statutory language of PPACA and goes beyond congressional intent by undercutting the internal process and diminishing the value of the investigations and determinations made by the plan.

4. Requirements to contract with 3 accredited IROs will be difficult to satisfy

Interim Procedures for Federal External Review require that self-insured group health plans contract with at least three independent review organization (IROs) accredited by URAC (formerly the Utilization Review Accreditation Committee) or by a similar nationally-recognized accrediting organization to conduct external review.⁴⁸ Given that there are roughly 38 IROs fully accredited by URAC nationwide⁴⁹, it will be difficult for employers to find three such organizations to deal with given the number of affected health benefit plans. Although there may be other accredited IROs, it is not clear whether there is a sufficient number of IROs to handle the demand or which are qualified to perform both clinical and legal review. The shortage of available IROs shows again the impracticality of implementing the IFRs' unrealistic time frame and underscores that the standard regulatory process should be followed for these regulations.

5. Failure to Address Important IRO Issues for ERISA Plans

The IFRs do not discuss the apparent ERISA fiduciary duties that IROs will be performing if their decisions are final and binding and subject only to review in court. Indeed, according to the IFRs, plans must pay the claim if so directed by the IRO. Under applicable ERISA principles, the IROs are making decisions regarding payment of plan assets and are therefore ERISA fiduciaries. This is a critical issue that the IFRs ignore. If an IRO makes an improper decision, the plan will experience a loss, and the IRO would appear to be liable if it breached any ERISA fiduciary duty. This Pandora box of issues needs full comment and vetting in standard regulatory proceedings.

CONCLUSION

⁴⁸Technical Release 2010-01, Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review under the Patient Protection and Affordable Care Act, U.S. Department of Labor, August 23, 2010, Section A (3), page 4.

⁴⁹ According to the URAC Directory of Accredited Companies (available at: <http://www.urac.org/directory/DirectorySearch.aspx>)

The U.S. Chamber of Commerce is concerned with the procedures followed by the Departments in issuing this regulation as well as the substance contained in the IFRs. We respectfully request that the Departments withdraw this problematic Interim Final Regulation and reissue a revised regulation in the form of a proposed rule. We hope our comments provide constructive and critical feedback. We look forward to assisting the Departments to promulgate improved regulations that will assure the internal claims and appeals and external reviews are effective tools for securing benefits when due and minimizing the cost of resolving benefit disputes, as Congress must have intended.

Sincerely,



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